

Robert Greene Sterne  
Edward J. Kessler  
Jorge A. Goldstein  
David K.S. Cornwell  
Robert W. Esmond  
Tracy-Gene G. Durkin  
Michelle A. Cimbal  
Michael B. Ray  
Robert E. Sokohl  
Eric K. Steffe  
Michael Q. Lee  
Steven R. Ludwig  
John M. Covert  
Linda E. Alcorn  
Robert C. Minton  
Donald J. Featherstone  
Timothy J. Shea, Jr.  
Lawrence B. Bugalsky  
Michael V. Messinger  
Judith U. Kim

Patrick E. Garrett  
Jeffrey T. Hevry  
Heidi L. Kraus  
Eldora L. Ellison  
Thomas C. Fiala  
Albert L. Ferro  
Donald R. Banowitz  
Peter A. Jackman  
Teresa U. Medler  
Jeffrey S. Weaver  
Kendrick P. Patterson  
Vincent L. Capuano  
Brian J. Del Buono  
Virgil Lee Beaton  
Theodore A. Wood  
Elizabeth J. Haanes  
Joseph S. Ostroff  
Frank R. Cottingham  
Christine M. Hulter  
Rae Lynn P. Guest

George S. Bardmesser  
Daniel A. Klein  
Jason D. Eisenberg  
Michael D. Specht  
Andrea J. Kamaga  
Tracy L. Muller  
Jon E. Wright  
LuAnne M. DeSantis  
Ann E. Summerfield  
Aric W. Ledford  
Helene C. Carlson  
Cynthia M. Bouchez  
Timothy A. Doyle  
Gaby L. Longworth  
Lori A. Gordon  
Nicole D. Dretar  
Ted J. Ebersole  
Jyoti C. Iyer  
Laura A. Vogel

Michael J. Mancuso  
Bryan S. Wade  
Aaron L. Schwartz  
Michael G. Penn  
Shannon A. Carroll  
Wesley W. Jones  
Matthew E. Kelley  
Nicole R. Kramer

**Registered Patent Agents\***  
Karen R. Markowicz  
Nancy J. Leth  
Matthew J. Dowd  
Katrina Yujian Pei Quach  
Bryan L. Skelton  
Robert A. Schwartzman  
Teresa A. Colella  
Jeffrey S. Lundgren  
Victoria S. Rutherford

Michelle K. Holoubek  
Simon J. Elliott  
Julie A. Heider  
Mita Mukherjee  
Scott M. Woodhouse  
Christopher J. Walsh  
Lizana Di Nola-Baron  
Peter A. Socarras  
Jeffrey Mills

**Of Counsel**  
Kenneth C. Bass III  
Evan R. Smith  
Marvin C. Guthrie

\*Admitted only in Maryland  
\*Admitted only in Virginia  
•Practice Limited to Federal Agencies

April 1, 2005

**WRITER'S DIRECT NUMBER:**  
(202) 772-8619

**INTERNET ADDRESS:**  
SCHWARTZ@SKGF.COM

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Mail Stop: Amendment  
Art Unit 1653**

Re: U.S. Utility Patent Application  
Application No. 10/633,698; Filed: August 5, 2003  
For: **Methods and Compounds for the Treatment of Mucus Hypersecretion**  
Inventors: Quinn *et al.*  
Our Ref: 1581.0770001/RWE/ALS

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Fourth Supplemental Information Disclosure Statement Under 37 C.F.R. § 1.97(b);
2. Four (4) pages of Form PTO-1449 citing fifteen (15) documents;
3. Copies of six (6) cited documents; and
4. One (1) return postcard.

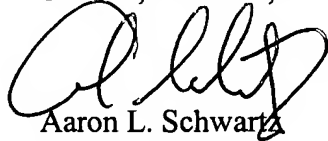
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
April 1, 2005  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read 'A. Schwartz', is written over the printed name.

Aaron L. Schwartz  
Attorney for Applicants  
Registration No. 48,181

RWE/ALS:law  
Enclosures  
381950v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Quinn *et al.*

Appl. No.: 10/633,698

Filed: August 5, 2003

For: **Methods and Compounds for the  
Treatment of Mucus  
Hypersecretion**

Confirmation No.: 5476

Art Unit: 1653

Examiner: Kam, Chih Min

Atty. Docket: 1581.0770001/RWE/ALS

**Fourth Supplemental Information Disclosure Statement  
Under 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

***Mail Stop: Amendment  
Art Unit 1653***

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Fourth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Third Supplemental Information Disclosure Statement filed on August 5, 2003, in connection with the above-captioned application.

Copies of documents AS10 to AR12 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents AE1 to AJ1, cited on the attached Form PTO-1449 are not submitted. In addition, copies of documents AS12 to AR13 are not provided in accordance with the U.S. Patent and Trademark Office OG notice of October 19, 2004, which states: "the requirement in 37 C.F.R. § 1.98(a)(2)(iii) for a legible copy of the specification, including the claims, and drawings of each cited pending U.S. patent application (or portion of the application which caused it to be listed) is sua sponte waived where the cited pending application is stored in the USPTO's IFW system."

The Examiner's attention is directed to documents AE1-AJ1, which are directed to related technical subject matter. The Examiner's attention is also directed to documents AS10-AR13, which are prosecution histories or applications of previously filed or co-pending patent applications which are directed to related technical subject matter. The identification of these U.S. Patent Applications and their respective prosecution histories is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

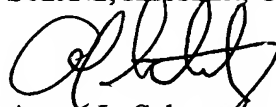
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

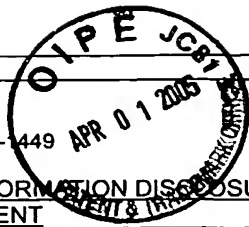
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read 'A. Schwartz', is written over the printed name.

Aaron L. Schwartz  
Attorney for Applicants  
Registration No. 48,181

Date: April 1, 2005

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600



FORM PTO-1449

ATTY. DOCKET NO.  
1581.0770001/RWE/ALSAPPLICATION NO.  
10/633,698FIRST NAMED INVENTOR  
Quinn *et al.*FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENTFILING DATE  
August 5, 2003ART UNIT  
1653

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE1	6,395,513 B1	05/28/2002	Foster <i>et al.</i>			
	AF1	6,461,617 B1	10/08/2002	Shone <i>et al.</i>			
	AG1	6,632,440 B1	10/14/2003	Quinn <i>et al.</i>			
	AH1	2003/0049264 A1	03/13/2003	Foster <i>et al.</i>			
	AI1	2003/0147895 A1	08/07/2003	Shone <i>et al.</i>			
	AJ1	2003/0166238 A1	09/04/2003	Shone <i>et al.</i>			
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS	10	Copy of application and Prosecution History for "Recombinant Toxin Fragments," Shone <i>et al.</i> , U.S. Application No. 09/255,829, filed February 23, 1999
	AT	10	Copy of Application and Prosecution History for "Conjugates of Galatose-Binding Lectins and Clostridial Neurotoxins as Analgesics," Duggan <i>et al.</i> , U.S. Application No. 09/529,130, with a §371 date June 22, 2000

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1581.0770001/RWE/ALS	APPLICATION NO. 10/633,698
	FIRST NAMED INVENTOR Quinn <i>et al.</i>	
	FILING DATE August 5, 2003	ART UNIT 1653

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>11</u>	Copy of Application and Prosecution History for "Methods and Compounds for the Treatment of Mucus Hypersecretion," Quinn <i>et al.</i> , U.S. Application No. 09/763,669, with a §371 date May 29, 2001
	AS	<u>11</u>	Copy of Application and Prosecution History for "Delivery of Superoxide Dismutase to Neuronal Cells," Shone <i>et al.</i> , U.S. Application No. 09/831,050, with a §371 date of August 20, 2001
	AT	<u>11</u>	Copy of Application and Prosecution History for "Constructs for Delivery of Therapeutic Agents to Neuronal Cells," Shone <i>et al.</i> , U.S. Application No. 10/130,973, with a §371 date of June 25, 2002

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1581.0770001/RWE/ALS	APPLICATION NO. 10/633,698
	FIRST NAMED INVENTOR Quinn <i>et al.</i>	
	FILING DATE August 5, 2003	ART UNIT 1653

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	12	Copy of Application and Prosecution History for "Recombinant Toxin Fragments," Shone <i>et al.</i> , U.S. Application No. 10/241,596, filed September 12, 2002
	AS	12	Shone <i>et al.</i> , "Delivery of Superoxide Dismutase to Neuronal Cells," U.S. Application No. 11/062,471, filed February 22, 2005
	AT	12	Shone <i>et al.</i> , "Recombinant Toxin Fragments," U.S. Patent Application No. 11/077,550, filed March 11, 2005

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



FORM PTO-1449  FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1581.0770001/RWE/ALS	APPLICATION NO. 10/633,698
	FIRST NAMED INVENTOR Quinn <i>et al.</i>	
	FILING DATE August 5, 2003	ART UNIT 1653

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	13	Shone <i>et al.</i> , "Recombinant Toxin Fragments," U.S. Patent Application No. 10/527,411, filed March 11, 2005
	AS		
	AT		

EXAMINER	DATE CONSIDERED
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	